



US005591736A

United States Patent [19]**Walser****[11] Patent Number:** **5,591,736****[45] Date of Patent:** **Jan. 7, 1997****[54] METHOD OF RETARDING THE PROGRESSION OF CHRONIC RENAL FAILURE****[75] Inventor:** **Mackenzie Walser**, Ruxton, Md.**[73] Assignee:** **The Johns Hopkins University**, Baltimore, Md.**[21] Appl. No.:** **497,958****[22] Filed:** **Jul. 3, 1995****[51] Int. Cl.⁶** **A61K 31/56****[52] U.S. Cl.** **514/178****[58] Field of Search** **514/178****[56] References Cited****U.S. PATENT DOCUMENTS**

| | | | | |
|-----------|---------|---------------|-------|------------|
| 4,100,160 | 7/1978 | Walser | | 424/274 |
| 4,228,099 | 10/1980 | Walser | | 260/501.11 |
| 4,352,814 | 10/1982 | Walser | | 424/273 R |
| 4,496,556 | 1/1985 | Orentreich | | 514/178 |
| 4,542,129 | 9/1985 | Orentreich | | 514/178 |
| 4,752,619 | 6/1988 | Walser et al. | | 514/564 |
| 5,175,144 | 12/1992 | Walser | | 514/2 |

OTHER PUBLICATIONS

Abstract (Accession Number QD586-0004) of Araneo et al., "Dehydroepiandrosterone Functions as More than an Anti-glucocorticoid in Preserving Immunocompetence after Thermal Injury" *Endocrinology* 136(2): 393-401 (Feb. 1995).

Kalimi et al., "Anti-Glucocorticoid Effects of Dehydroepiandrosterone (DHEA)", *Mol. Cell. Biochem.* 131:99-104 (1994).

Lucas et al., "Prevention of Autoantibody Formation and Prolonged Survival in New Zealand Black/New Zealand White F₁ Mice Fed Dehydroisoandrosterone", *J. Clin. Invest.* 75:2091-2093 (1995).

McIntosh et al., "Strain Differences in the Dose-Response Curves of Adrenalectomized, Starved-Refed Rats to Dehydroepiandrosterone (DHEA) (42657)", *Proc. Soc. Exp. Biol. Med.* 187:216-222 (1988).

Meikle et al., "The Presence of a Dehydroepiandrosterone-Specific Receptor Binding Complex in Murine T Cells", *J. Steroid Biochem. Molec. Biol.* 42(3/4):293-304 (1992).

Meikle et al., "Adrenal Androgen Secretion and Biologic Effects", *Endocrinol. Metab. Clinics N. Amer.* 20(2):381-400 (1991).

Pashko et al., "Inhibition of Proteinuria Development in Aging Sprague-Dawley Rats and C57BL/6 Mice by Long-Term Treatment with Dehydroepiandrosterone", *J. Gerontol.* 41(4):433-438 (1986).

Suzuki et al., "Dehydroepiandrosterone Enhances IL2 Production and Cytotoxic Effector Function of Human T Cells", *Clin. Immunol. Immunopath.* 61:202-211 (1991).

Svec et al., "The Effect of DHEA Given Chronically to Zucker Rats (43883)", *Proc. Soc. Exp. Biol. Med.* 209:92-97 (1995).

van Vollenhoven et al., "An Open Study of Dehydroepiandrosterone in Systemic Lupus Erythematosus", *Arthritis Rheum.* 37(9): 1305-1310 (1994).

Walser et al., "Progression of Chronic Renal Failure is Related to Glucocorticoid Production", *Kidney Int.* 34:859-866 (1988).

Walser et al., "Progression of Chronic Renal Failure in Patients Given Ketoacids Following Amino Acids", *Kidney Int.* 32:123-128 (1987).

Winer et al., "Preservation of Normal Adrenal Androgen Secretion in End Stage Renal Disease", *Metabolism* 31(3):269-273 (1982).

Zumoff et al., "Subnormal Plasma Adrenal Androgen Levels in Men with Uremia", *J. Clin. Endocrin. Metab.* 51(4):801-805 (1980).

Primary Examiner—Raymond Henley, III

Attorney, Agent, or Firm—Panitch, Schwarze, Jacobs & Nadel, P.C.

[57]**ABSTRACT**

The progression of chronic renal failure in humans may be retarded by administration of dehydroepiandrosterone (DHEA) in effective amounts. The administration of DHEA is preferably oral at a dose of about 400 to 1600 mg/day. Patients suffering from severe chronic renal failure are also preferably maintained on a protein-restricted diet during DHEA administration.

12 Claims, No Drawings